K062131

510(K) SUMMARY

In accordance with 21 CFR 807.92

1. Date of preparation

July, 22 2006

2. Company information

NOV 17 2006

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: Nio 5MP-M-21"
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: Coronis 5MP
- 510(k) number: K042221
- Manufacturer: Barco NV

6. Device description

Nio 5MP-M-21" is a display system for medical viewing. It consists of 3 components:

MDNG-5121 BB is a 21.3" grayscale LCD display. BarcoMed Nio is a fast high-resolution display controller board that plugs into a PACS workstation computer. NioWatch is a softcopy QA software application for local calibration and QA control.

The display system can be a single-head system or multi-head system. In the last case it contains multiple displays and display controller boards.

7. Intended use

"The Nio 5MP-M-21" is intended to be used in displaying and viewing digital images, including digital mammography, for review and analasys by trained medical practitioners.

8. Summary of technological characteristics

The device consists of three components:

- One 5-megapixel flat panel display (MDNG-5121 BB)
- One 10-bit display controller (BarcoMed Nio board)
- NioWatch software

The flat panel display has a resolution of 2560x2048 pixels. It can be used in landscape and portrait mode.

The BarcoMed Nio display controller board is an ultra-high speed board with a 8-bit in, 10-bit out lookup table, providing 256 simultaneous shades of gray.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the display from the Nio 5MP-M-21" system uses the same LCD panel but does not have a built-in front sensor (I-Guard). The accompanying software application has a lower functionality. However, the basic specifications and functions of both systems are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:

The Barco Nio 5MP-M-21" is substantially equivalent to the predicate device, Coronis 5MP.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco Nio 5MP-M-21" contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Lieven De Wandel
Official Correspondent
Barco-Medical Imaging Systems
President Kennedypark 35
B-8500 Kortrijk
BELGIUM

NOV 17 2006

Re: K062131
Trade/Device Name: MDNG-5121 BB
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 9, 2006
Received: October 11, 2006

Dear Mr. De Wendel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062131

Device Name: MDNG-5121 BB

Indications for Use:

"The MDNG-5121 BB is intended to be used in displaying and viewing digital images, including digital mammography, for review and analasys by trained medical practitioners.

Prescription Use __XX___

(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062131